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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,105	10/04/2001	Howard Milne Chandler	0141-2006	3619

7590 05/19/2004  
 Kevin M Farrell  
 One New Hampshire Avenue  
 Suite 350  
 Portsmouth, NH 03801

EXAMINER

NGUYEN, BAO THUY L

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/856,105	<b>Applicant(s)</b> CHANDLER ET AL.	
	<b>Examiner</b> Bao-Thuy L. Nguyen	<b>Art Unit</b> 1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Priority*

1. Acknowledgement is made of a claim for foreign priority under 35 USC § 119(a)-(d) or (f).

All certified copies of the priority documents have been received.

### *Claim Rejections - 35 USC § 112*

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because it lacks a correlation step.

Claim 14 is indefinite because it fails to properly correlate the result of the test. For example, the preamble recites a method of detecting *upper* gastrointestinal tract bleeding, yet the result is recited as being indicative of *lower* gastrointestinal tract bleeding.

Claim 20 is indefinite because it lacks a correlation between the detected result and the diagnosis of a diseased condition.

It is recommended that “haem” be replaced with the more conventional -heme— for clarity.

### *Claim Rejections - 35 USC § 112, first paragraph*

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-26 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The use of a labeled binding partner and an immobilized capture binding partner is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Page 14 of the specification teaches a chromatographic test strip comprising a first region for receiving a biological sample, and a second region that comprises two sections. The first section of the second region is an area of immobilized antiglobin antibody coupled to colloidal gold particles that are re-suspendible and the second area is an area of immobilized antiglobin capture antibody. The third region comprises an absorbent pad impregnated with guaiac. The use of the labeled binding partner enables detection of any assay complex and the use of the capture binding partner immobilized the complex in a detection area. Such labels and capture reagents are not recited in the claims.

6. Claims 8-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8 and 14 recite methods for the detection of lower and upper gastrointestinal bleeding, respectively. However, the method steps in each of these claims are the same as are the analytes being detected. Therefore, it is unclear how one may differentiate between upper

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and lower gastrointestinal bleeding from the result of the assay. Furthermore, the specification lacks any specific description of how one may determine whether the subject under testing suffers from either upper or lower gastrointestinal bleeding by detecting globin and heme. Given the complete and total lack of description in the specification, the claims fail to comply with the written description requirement because the subject matter was not described in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed.

*Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allison et al (The New England Journal of Medicine. Vol. 334, No. 3, pp. 155-159. 1996) in view of Kuo et al (US 6,436,721) and Sy (WO 98/33069).

Allison discloses a screening test for colorectal neoplasms comprising a guaiac test for fecal occult blood (heme activity) and an immunochemical test for human hemoglobin in a fecal sample. Allison discloses specimen cards containing a set of three different tests, Hemoccult II (a guaiac test for fecal occult blood), Hemoccult II Sensa (a more sensitive guaiac test for heme) and HemeSelect, (an immunochemical test for human hemoglobin using anti-human

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hemoglobin antibody). Allison discloses that the combination between Hemoccult II Sensa and HemeSelect has the highest specificity as well as highest sensitivity for detecting neoplasms.

See pages 155-156.

Allison differs from the instant invention in failing to teach the use of a lateral flow chromatographic medium for the detection of occult blood.

Kuo, however, discloses the use of a flow matrix for detecting pairs of clinically related analyte. See column 2, line 24 through column 3, line 23. Kuo discloses that immunochromatographic test strips are ideal for providing a viable system for the determination of various analytes and provide quick and convenient means of determining those second analytes whose concentration or presence in the body fluid sample is clinically related to the concentration of the target analyte. See column 8, lines 8-12.

And Sy discloses a chromatographic medium for detecting analytes such as occult blood in a fecal sample. Pages 24-26.

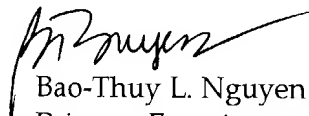
Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the method taught by Allison in order to simultaneously detect globin, using an immunochemical test, and heme, using a guaiac test, on the device of Kuo because Sy teaches that chromatographic medium are adaptable for detection of occult blood and analytes from a fecal samples. A skilled artisan would have had a reasonable expectation of success in adapting the device of Kuo as taught by Sy to detect globin and heme because Allison teaches that an ideal screening test would be highly sensitive and specific, as well as effective in decreasing morbidity and mortality, and that a combination test for heme and globin incorporates the best features of the various tests for colorectal-cancer screening (Allison, page 158).

*Conclusion*

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
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